REMARKS

The final Office Action of May 4, 2006, has been received and reviewed.

Claims 6-49 are currently pending and under consideration in the above-referenced application, each standing rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Claims 6-49 have been rejected under 35 U.S.C. §103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant=s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Howson in View of Johnson

Claims 6, 8-10, 12-19, 22-30, 35, 36, and 41-49 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is allegedly obvious in view of teachings from U.S. Patent 5,088,981 to Howson (hereinafter "Howson") and U.S. Patent 5,522,798 to Johnson et al. (hereinafter "Johnson").

Independent claim 6, as proposed to be amended, is directed to a system for data representation. Among other things, the system of amended independent claim 6 includes a drug display monitor. The drug display monitor of amended independent claim 6 is configured to depict, in real time, a present "probability of effectiveness" of at least one drug introduced into the subject by the drug delivery system and future "probabilities of effectiveness" of the one or more drugs in the subject.

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Independent claim 14, as proposed to be amended, recites a system for data representation that includes, among other things, a display monitor that is configured to depict, graphically and substantially in real-time, a modeled "probability of effectiveness" of at least one drug in a subject. The "probability of effectiveness" includes a probability that the at least one drug will cause the subject to lose consciousness, a probability of eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain experienced by the subject, and a probability of causing a measurable level of muscle relaxation in the subject

Independent claim 35, as proposed to be amended, is drawn to a system for modeling a probability of desired effectiveness of at least one drug in a subject. The system of amended independent claim 35 includes a processing element and an output element. The processing element is programmed to model a concentration of at least one drug in a subject over time. The output element is configured to display, substantially in real-time, a modeled concentration of the at least one drug "in reference to at least one concentration at which the at least one drug will have a desired effect" on a known percentage of a population.

The teachings of Howson relate to portable drug delivery devices that may be programmed to deliver drugs in accordance with "pharmacokinetic, pharmacodynamic, or dose-response models . . . to either aid programming of the delivery profile . . . or to simulate the outcome of a profile in terms of resulting bodily concentrations . . ." Col. 7, lines 37-43.

Johnson also teaches portable drug delivery devices. The portable drug delivery devices of Johnson may be programmed to deliver drugs in accordance with a model that controls a blood plasma drug concentration or an effect compartment drug concentration (*i.e.,* the concentration of a drug at a particular location in a patient's body – *see, e.g.,* col. 9, line 47, to col. 14, line 64) in a desired manner. Col. 3, lines 26-34.

It is respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 6, 8-10, 12-19, 22-30, 35, 36, or 41-49 since neither Howson nor Johnson, taken either alone or together, teaches or suggests each and every element of any of these claims.

In particular, with respect to amended independent claims 6 and 14, Howson and Johnson both lack any teaching or suggestion of a drug display monitor that is configured to depict, graphically and substantially in real time, a probability of effectiveness of at least one drug. Instead

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of displaying the probability that a drug will have a particular effect on a subject, the teachings of Howson and Johnson are limited to displaying raw concentration data, which would not provide the same type of easy-to-understand indicator of the effectiveness of the drug on a subject.

Further, with respect to amended independent claim 14, it is respectfully submitted that neither Howson nor Johnson teaches or suggests a system with a drug display monitor that is configured to depict a probability of effectiveness of at least one drug at causing a subject to lose consciousness, at eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain, or at causing a measurable level of muscle relaxation in the subject. Again, the teachings of Howson and Johnson are limited to providing raw concentration data, and include no mention of effectiveness data, particularly with respect to the factors recited in amended independent claim 14.

As for the system of independent claim 35, it is respectfully submitted that Howson and Johnson both lack any teaching or suggestion that a modeled concentration of at least one drug "in reference to at least one concentration at which the at least one drug will have a desired effect" on a known percentage of a population. Again, the teachings of Howson and Johnson are limited to providing raw concentration information for a drug without any indication of the probability that the drug will have a desired effect on a particular percentage of a population, or on subject to whom the drug is administered. In fact, the formulas presented in TABLE 1 of Johnson, which begins at col 15, line 16, thereof, are tailored to provide information on raw drug concentrations in certain effect compartments.

Each of claims 8-10, 12, 13, 16-19, and 41-43 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 6, which is allowable.

Claim 12 is additionally allowable because neither Howson nor Johnson includes any teaching or suggestion of a system that includes a normalizer. Rather, the teachings of Howson and Johnson are limited to system that are configured to model and, optionally, display raw (*i.e.,* non-normalized) drug concentration data.

Claim 16 is also allowable since neither Howson nor Johnson teaches or suggests a system that includes a drug display monitor that depicts a probability of effectiveness of a drug as a percent likelihood that the at least one drug has a desired effect. Again, the teachings of Howson and

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Johnson are limited to devices that depict raw drug concentrations rather than the probability that the manner in which a particular drug is administered will have a certain effect on a subject.

Claim 17, which depends from claim 16, is additionally allowable because Howson and Johnson include no teaching or suggestion of a system with a drug display monitor that depicts a probability of effectiveness of a drug as a percent likelihood based on results from a predefined population.

Claim 18 is further allowable since the systems of Howson and Johnson lack display monitors that depict a line representing a concentration at which there is a ninety-five percent probability the at least one drug will have a desired effect.

Claim 19 depends from claim 18 and is also allowable since neither Howson nor Johnson includes any teaching or suggestion of a system with a display monitor that depicts a line that provides a point of reference for a clinician.

Claim 43 is further allowable since Howson and Johnson both lack any teaching or suggestion of a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

Claims 15, 22-30, and 44-46 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 14, which is allowable.

Claim 27 is also allowable since neither Howson nor Johnson teaches or suggests a system that includes a drug display monitor that depicts a probability of effectiveness of a drug as a percent likelihood that the at least one drug has a desired effect. Again, the teachings of Howson and Johnson are limited to devices that depict raw drug concentrations rather than the probability that the manner in which a particular drug is administered will have a certain effect on a subject.

Claim 28, which depends from claim 27, is additionally allowable because Howson and Johnson include no teaching or suggestion of a system with a drug display monitor that depicts a probability of effectiveness of a drug as a percent likelihood based on results from a predefined population.

Claims 29 and 30 are further allowable since the system of each of Howson and Johnson lacks a display monitor that depicts an element representing a concentration at which there is a ninety-five percent probability the at least one drug will have a desired effect.

Claim 46 is further allowable since Howson and Johnson both lack any teaching or suggestion of a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

Claims 36 and 47-49 are each allowable, among other reasons, for depending directly or indirectly from amended independent claim 35, which is allowable.

Claim 49 is further allowable since Howson and Johnson both lack any teaching or suggestion of a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

It is further submitted that, in view of the fact that neither Howson nor Johnson teaches or suggests each and every element of any of claims 6, 8-10, 12-19, 22-30, 35, 36, or 41-49, without the benefit of hindsight that has been provided to the Office by the claims of the above-referenced application, one of ordinary skill in the art wouldn't have been motivated to combine teachings from Howson and Johnson in the asserted manner or had any reason to expect that the asserted combination of reference teachings would have been successful.

As a *prima facie* case of obviousness has not been set forth against any of claims 6, 8-10, 12-19, 22-30, 35, 36, or 41-49, it is respectfully submitted that each of these claims is directed to subject matter that, under 35 U.S.C. §103(a), is allowable over the teachings of Howson and Johnson.

Howson in View of Teeple

Claims 7 and 11 have been rejected under 35 U.S.C. §103(a) for reciting subject matter that is purportedly unpatentable over the teachings of Howson, in view of the subject matter taught in U.S. Patent 5,925,014 to Teeple, Jr. (hereinafter "Teeple").

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Claims 7 and 11 are both allowable, among other reasons, for depending directly or indirectly from amended independent claim 6, which is allowable.

Howson, Johnson, and Teeple

Claims 20, 21, 31-34, and 37-40 are rejected under 35 U.S.C. §103(a) for being directed to subject matter which is assertedly unpatentable over the subject matter taught in Howson, in view of teachings from Johnson and, further, in view of the teachings of Teeple.

Claims 20 and 21 are both allowable, among other reasons, for depending directly or indirectly from amended independent claim 6, which is allowable.

Claim 21 is further allowable since none of Howson, Johnson, or Teeple teaches or suggests a system with a drug display monitor that is configured to depict a probability of effectiveness of a course of anesthesia at causing the subject to lose consciousness, at eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain, and at causing a measurable level of muscle relaxation in the subject.

Each of claims 31-34 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 14, which is allowable.

Claim 31 is additionally allowable since none of Howson, Johnson, or Teeple teaches or suggests a system with a process that is configured to model a probability of effectiveness of at least two anesthetic agents at causing the subject to lose consciousness, at eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain, or at causing a measurable level of muscle relaxation in the subject.

Claims 37-40 are each allowable, among other reasons, for depending directly or indirectly from amended independent claim 35, which is allowable.

Claim 37 is also allowable because none of Howson, Johnson, or Teeple teaches or suggests a system with a processing element that is configured to model a desired effect in terms of the abilities of at least two anesthetic agents to cause a subject to lose consciousness, to eliminate or block laryngoscopy pain, incision pain, or intraoperative pain, or to cause a measurable level of muscle relaxation in the subject.

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It is respectfully requested that the 35 U.S.C. §103(a) rejections of claims 6-49 be withdrawn and that each of these claims be allowed.

Provisional Statutory and Obviousness-Type Double Patenting Rejections

It is respectfully requested that the provisional double patenting rejections that were presented in the outstanding Office Action be held in abeyance until the other issues that have been presented are resolved.
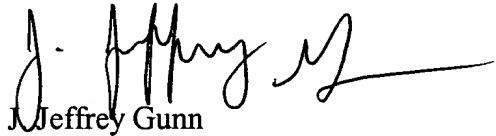
Entry of Amendments

Entry of the proposed amendments to the claims is respectfully solicited. It is respectfully submitted that the proposed claim amendments do not introduce new matter into the above-referenced application, nor would they necessitate an additional search.

In the event that the proposed claim amendments are not entered, their entry is respectfully requested upon the filing of a Notice of Appeal in the above-referenced application.

CONCLUSION

It is respectfully submitted that each of claims 6-49 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

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Date: August 4, 2006
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